

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kikuchi et al.

Application No.: **10/673,860**

Filing Date: 30 September 2003

For: METHODS FOR SECRETORY
PRODUCTION OF PROTEINS

Art Unit: 1661

Examiner: Nancy Vogel

Attorney Ref. No.: US-111

REPLY BRIEF FOR APPELLANT

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

COMES NOW the Appellant to present this Reply Brief in compliance with 37 C.F.R. §41.41. This Reply Brief is in response to the Examiner's Answer mailed March 7, 2006. A petition for an extension of time is not necessary, as reply brief is filed with 2 months of the mailing date of the Examiner's Answer.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application or dismissal of this appeal, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to Deposit Account No. 50-2821.

For the following reasons, Appellant respectfully submits that the final rejection of each of Claims 1, 3, 4, 7, 8, 10, and 11 in this application continues to be in error, and therefore respectfully requests reversal of the rejections.

I. Real Party in Interest

See Appeal Brief filed November 30, 2005.

II. Related Appeals and Interferences

See Appeal Brief filed November 30, 2005.

III. Status of Claims

See Appeal Brief filed November 30, 2005.

IV. Status of Amendments

See Appeal Brief filed November 30, 2005.

V. Summary of Invention

See Appeal Brief filed November 30, 2005.

VI. Issues

See Appeal Brief filed November 30, 2005.

VII. Grouping of Claims

See Appeal Brief filed November 30, 2005.

VIII. Argument

In the Examiner's Answer dated 07 March 2006, beginning at page 5, The Examiner asserts that even those skilled in the art could not envision a mutant of AJ12036 because the genetic structure which is responsible for the increased secretion of proteins in AJ12036 is not disclosed in the specification and therefore those skilled in the art could not know the identity of the structure responsible which must be maintained in the claimed mutant. However, it should be noted that AJ12036 has been deposited at the time of filing date as FERM BP734 (see page 10, line

11). There is no requirement to “envision” the structure of the mutant since it has been deposited. It has been previously recognized that due to the practical difficulties of describing unique biological materials, reference in the specification to a deposit in a public depository, which makes its contents available to the public, may constitute an adequate written description. Therefore, the Examiner’s call for structural information regarding the claimed activity of increased secretion is unfounded, since the strain possessing such activity has been deposited and all required statements and assurances have been provided.

Regarding the “mutants thereof”, again said language only encompasses mutants of the deposited strain which maintain the claimed activity. Assays for determining such activity are clearly described in the specification and within the skill of the skilled art worker. The Examiner has maintained that no mutants are described; however, this is simply not true. In Example 9 of the specification (p. 53), a mutation to deposited strain AJ12036 which results in disruption of the gene which encodes cell surface protein PS2 is well described; precisely, a mutant strain, YDK010, which is missing 1,029 bases in the promoter and N-terminus of the coding region of the PS2 gene was obtained based on common technical knowledge. The number of missing bases is calculable based on the primer construction as used in Examples. The property of the strain for increased secretion is maintained despite this mutation. Using any known method such as the exemplified one above, the skilled art worker would be able to easily envision and obtain mutated strains which maintain the claimed activity in the absence of a description of the genetic construction of the parent strain, and hence mutated strains are sufficiently described.

Furthermore, the Examiner argues that the term “mutant” includes more than point mutations, but may include large deletions of genes. However, one of skill in the art would know that such large deletions might disrupt the functioning of the strain, and particularly the secretion ability, and therefore, would be outside the scope of the claims. Only minor mutations which do not disrupt the functioning of the cell, and particularly which do not disrupt the ability of the cell to secrete the heterologous protein 2-fold larger than ATCC13869, are encompassed within the scope of the claims. Therefore, appellants stress that the genus is actually quite small, and readily assayable by the person of skill in the art.

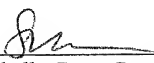
In summary, due to the deposit of the AJ12036 strain, and the small number of mutants which are envisioned based upon the high skill in this art, the deposit of the 'starting material', and the ease of assaying the potential mutants, it is clear that appellants were in full possession of the invention as claimed.

For at least the reasons presented herein, each of the subject matters of Claims 1, 3, 4, 7, 8, 10, and 11, taken as a whole, are patentable and meet the written description requirement of 35 U.S.C. §112, 1st paragraph. Accordingly, the rejection of each of Claims 1, 3, 4, 7, 8, 10, and 11 under section 112, 1st paragraph is reversible error.

IX. Conclusion

For at least the foregoing reasons, Appellant respectfully submits that the subject matters of Claims 1, 3, 4, 7, 8, 10, and 11, each taken as a whole, are patentable. Accordingly, Appellant respectfully requests reversal of the rejections of Claims 1, 3, 4, 7, 8, 10, and 11 under section 112, 1st paragraph.

Respectfully submitted,

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